Antiplatelet drug

From Wikipedia, the free encyclopedia

An **antiplatelet drug** is a member of a class of pharmaceuticals that decreases **platelet** aggregation and inhibits thrombus formation. They are effective in the arterial circulation, where anticoagulants have little effect.

They are widely used in primary and secondary prevention of thrombotic cerebrovascular or cardiovascular disease.

Choice of antiplatelet drug

A recent review [1] (http://www.amjmed.com/article/PIIS0002934305010430/abstract) states: "....low-dose aspirin increases the risk of major bleeding 2-fold compared with placebo. However, the annual incidence of major bleeding due to low-dose aspirin is modest—only 1.3 patients per thousand higher than what is observed with placebo treatment. Treatment of approximately 800 patients with low-dose aspirin annually for cardiovascular prophylaxis will result in only 1 additional major bleeding episode."

Antiplatelet drugs

The most important antiplatelet drugs are:

- Cyclooxygenase inhibitors
  - Aspirin
- Adenosine diphosphate (ADP) receptor inhibitors
  - Clopidogrel (Plavix)
  - Ticlopidine (Ticlid)
- Phosphodiesterase inhibitors
  - Cilostazol (Pletal)
- Glycoprotein IIB/IIIA inhibitors (intravenous use only)
  - Abciximab (ReoPro)
  - Eptifibatide (Integrilin)
  - Tirofiban (Aggrastat)
  - Defibrotide
- Adenosine reuptake inhibitors

- Dipyridamole (Persantine)

See also

- Anticoagulant drug
- Thrombolytic drug
- Antiaggregants

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MPEP Section 2138.05, "Reduction to Practice"

EXECUTIVE SUMMARY:

This document contains one section of the Manual of Patent Examining Procedure (the "**M.P.E.P.**"), Eighth Edition, Fifth Revision (August 2006). This page was last updated in July 2007. You may return to the section index to find a particular section. Alternatively, you may search the **MPEP** use the search box that appears on the bottom of every page of BitLaw--be sure to restrict your search to the **MPEP** in the pop-up list.

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2138.05 "Reduction to Practice"

Reduction to **practice** may be an actual **reduction** or a constructive **reduction** to **practice** which occurs when a patent application on the claimed invention is filed. The filing of a patent application serves as conception and constructive **reduction** to **practice** of the subject matter described in the application. Thus the inventor need not provide evidence of either conception or actual **reduction** to **practice** when relying on the content of the patent application. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998). A **reduction** to **practice** can be done by another on

Physiol. Res. 44 (2): 93-98, 1995 PHYSIOLOGICAL RESEARCH

Radioprotective Efficacy of Dipyridamole and AMP Combination in Fractionated Radiation Regimen, and Its Dependence on the Time of Administration of the Drugs Prior to Irradiation

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Summary
We have recently demonstrated that the combined administration of dipyridamole and adenosine monophospate to mice induces radioprotective effects in terms of postirradiation haemopoietic recovery in animals irradiated with a single dose. The aim of the present experiments was to investigate the radioprotective ability of the drug combination under conditions of fractionated radiation treatment. It has been shown that administration of drugs either 15 or 60 min before each of the five daily 3-Gy doses of gamma-radiation enhances haemopoietic recovery and survival of mice exposed to an additional "top-up" dose of 3.5 Gy. Furthermore, it has been ascertained that the regimen using administration of the drugs 60 min prior to irradiation is more effective than administration of the drugs 15 min prior to irradiation. Due to the evidence that administration of the drugs 15 min prior to irradiation protects the organism mainly via mechanisms of systemic hypoxia while the pretreatment 60 min before irradiation avoids the role of hypoxia and mainly induces cell proliferation effects, our results suggest a more effective protective role of mechanisms stimulating haemopoiesis under conditions of fractionated radiation. The data may provide a basis for more rational use of radioprotection in fractionated radiation regimens.

Key words
Rdioprotection - Fractionated irradiation - Haemopoiesis - Adenosine monophosphate - Dipyridamole

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behalf of the inventor. *De Solms v. Schoenwald*, 15 USPQ2d 1507, 1510 (Bd. Pat. App. & Inter. 1990). "While the filing of the original application theoretically constituted a constructive **reduction** to **practice** at the time, the subsequent abandonment of that application also resulted in an abandonment of the benefit of that filing as a constructive **reduction** to **practice**. The filing of the original application is, however, evidence of conception of the invention." *In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 392 (Fed. Cir. 1983)(The second application was not co-pending with the original application and it did not reference the original application. Because of the requirements of 35 U.S.C. 120 had not been satisfied, the filing of the original application was not recognized as constructive **reduction** to **practice** of the invention.).

I. CONSTRUCTIVE REDUCTION TO PRACTICE REQUIRES COMPLIANCE WITH 35 U.S.C. 112, FIRST PARAGRAPH

When a party to an interference seeks the benefit of an earlier-filed U.S. patent application, the earlier application must meet the requirements of 35 U.S.C. 120 and 35 U.S.C. 112, first paragraph for the subject matter of the count. The earlier application must meet the enablement requirement and must contain a written description of the subject matter of the interference count. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998). Proof of a constructive **reduction** to **practice** requires sufficient disclosure under the "how to use" and "how to make" requirements of 35 U.S.C. 112, first paragraph. *Kawai v. Metlesics*, 480 F.2d 880, 886, 178 USPQ 158, 163 (CCPA 1973) (A constructive **reduction** to **practice** is not proven unless the specification discloses a practical utility where one would not be obvious. Prior art which disclosed an anticonvulsant compound which differed from the claimed compound only in the absence of a -CH

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- group connecting two functional groups was not sufficient to establish utility of the claimed compound because the compounds were not so closely related that they could be presumed to have the same utility.). The purpose of the written description requirement is "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978). The written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent application was filed. Furthermore, the written description must be sufficient, when the entire specification is considered, such that the "necessary and only reasonable construction" that would be given it by a person skilled in the art is one that clearly supports each positive limitation in the count. *Hyatt v. Boone*, 146 F.3d at 1354-55, 47 USPQ2d at 1130-1132 (Fed. Cir. 1998) (The claim could be read as describing subject matter other than that of the count and thus did not establish that the applicant was in possession of the invention of the count.). See also *Bigham v. Godtfredsen*, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) ("[t]he generic term halogen comprehends a limited number of species, and ordinarily constitutes a sufficient written description of the common halogen species," except where the halogen species are patentably distinct).

II. REQUIREMENTS TO ESTABLISH ACTUAL REDUCTION TO PRACTICE

"In an interference proceeding, a party seeking to establish an actual **reduction** to **practice** must satisfy a two-prong test: (1) the party constructed an embodiment or performed a process that met every element of the interference count, and (2) the embodiment or process operated for its intended purpose." *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

The same evidence sufficient for a constructive **reduction** to **practice** may be insufficient to establish an actual **reduction** to **practice**, which requires a showing of the invention in a physical or tangible form that shows every element of the count. *Wetmore v. Quick*, 536 F.2d 937, 942, 190 USPQ 223, 227 (CCPA 1976). For an actual **reduction** to **practice**, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a

commercially satisfactory stage of development. >See, e.g., *Scott v. Finney*, 34 F.3d 1058, 1062, 32 USPQ2d 1115, 1118-19 (Fed. Cir. 1994)(citing numerous cases wherein the character of the testing necessary to support an actual **reduction** to **practice** varied with the complexity of the invention and the problem it solved).< If a device is so simple, and its purpose and efficacy so obvious, construction alone is sufficient to demonstrate workability. *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985).

For additional cases pertaining to the requirements necessary to establish actual **reduction** to **practice** see *DSL Dynamic Sciences, Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1126, 18 USPQ2d 1152, 1155 (Fed. Cir. 1991) ("events occurring after an alleged actual **reduction** to **practice** can call into question whether **reduction** to **practice** has in fact occurred"); ** *Fitzgerald v. Arbib*, 268 F.2d 763, 765-66, 122 USPQ 530, 531-32 (CCPA 1959) ("the **reduction** to **practice** of a three-dimensional design invention requires the production of an article embodying that design" in "other than a mere drawing")>; *Birmingham v. Randall*, 171 F.2d 957, 80 USPQ 371, 372 (CCPA 1948) (To establish an actual **reduction** to **practice** of an invention directed to a method of making a product, it is not enough to show that the method was performed. "[S]uch an invention is not reduced to **practice** until it is established that the product made by the process is satisfactory, and [ ] this may require successful testing of the product.")<.

III. TESTING REQUIRED TO ESTABLISH AN ACTUAL REDUCTION TO PRAC-TICE

"The nature of testing which is required to establish a **reduction** to **practice** depends on the particular facts of each case, especially the nature of the invention." *Gellert v. Wanberg*, 495 F.2d 779, 783, 181 USPQ 648, 652 (CCPA 1974) ("an invention may be tested sufficiently ... where less than all of the conditions of actual use are duplicated by the tests"); *Wells v. Fremont*, 177 USPQ 22, 24-5 (Bd. Pat. Inter. 1972) ("even where tests are conducted under 'bench' or laboratory conditions, those conditions must 'fully duplicate each and every condition of actual use' or if they do not, then the evidence must establish a relationship between the subject matter, the test condition and the intended functional setting of the invention," but it is not required that all the conditions of all actual uses be duplicated, such as rain, snow, mud, dust and submersion in water).

IV. REDUCTION TO PRACTICE RE-QUIRES RECOGNITION AND APPRE-CIATION OF THE INVENTION

The invention must be recognized and appreciated for a **reduction** to **practice** to occur. "The rule that conception and **reduction** to **practice** cannot be established nunc pro tunc simply requires that in order for an experiment to constitute an actual **reduction** to **practice**, there must have been contemporaneous appreciation of the invention at issue by the inventor.... Subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention. However, evidence of subsequent testing may be admitted for the purpose of showing that an embodiment was produced and that it met the limitations of the count." *Cooper v. Goldfarb*, 154 F.3d 1321, 1331, 47 USPQ2d 1896, 1904 (Fed. Cir. 1998) (citations omitted). *Meitzner v. Corte*, 537 F.2d 524, 528, 190 USPQ 407, 410 (CCPA 1976) (there can be no conception or **reduction** to **practice** of a new form or of a process using such a new form of an otherwise old composition where there has been no recognition or appreciation of the existence of the new form); *Estee Lauder, Inc. v. L'Oreal S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997) ("[W]hen testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for **reduction** to **practice** to occur." A showing that testing was completed before the critical date, and that testing ultimately proved successful, was held insufficient to establish a **reduction** to **practice** before the critical date, since the success of the testing was not appreciated or recognized until after the critical date.); *Parker v. Frilette*, 462 F.2d 544, 547, 174 USPQ 321, 324 (CCPA 1972) ("[an] inventor need not understand precisely why his invention works in order to achieve an actual **reduction** to **practice**").

V. RECOGNITION OF THE INVENTION BY ANOTHER MAY INURE TO THE BENEFIT OF THE INVENTOR

"Inurement involves a claim by an inventor that, as a matter of law, the acts of another person should accrue to the benefit of the inventor." *Cooper v. Goldfarb*, 154 F.3d 1321, 1331, 47 USPQ2d 1896, 1904 (Fed. Cir. 1998). Before a non-inventor's recognition of the utility of the invention can inure to the benefit of the inventor, the following three-prong test must be met: (1) the inventor must have conceived of the invention, (2) the inventor must have had an expectation that the embodiment tested would work for the intended purpose of the invention, and (3) the inventor must have submitted the embodiment for testing for the intended purpose of the invention. *Genentech Inc. v. Chiron Corp.*, 220 F.3d 1345, 1354, 55 USPQ2d 1636, 1643 (Fed. Cir. 2000). In *Genentech*, a non-inventor hired by the inventors to test yeast samples for the presence of the fusion protein encoded by the DNA construct of the invention recognized the growth-enhancing property of the fusion protein, but did not communicate this recognition to the inventors. The court found that because the inventors did not submit the samples for testing growth-promoting activity, the intended purpose of the invention, the third prong was not satisfied and the uncommunicated recognition of the activity of the fusion protein by the non-inventor did not inure to their benefit. See also *Cooper v. Goldfarb*, 240 F.3d 1378, 1385, 57 USPQ2d 1990, 1995 (Fed. Cir. 2001) (Cooper sent to Goldfarb samples of a material for use in vascular grafts. At the time the samples were sent, Cooper was unaware of the importance of the fibril length of the material. Cooper did not at any time later convey to, or request from, Goldfarb any information regarding fibril length. Therefore, Goldfarb's determination of the fibril lengths of the material could not inure to Cooper's benefit.).

VI. IN AN INTERFERENCE PROCEEDING, ALL LIMITATIONS OF A COUNT MUST BE REDUCED TO PRACTICE

The device reduced to **practice** must include every limitation of the count. *Fredkin v. Irasek*, 397 F.2d 342, 158 USPQ 280, 285 (CCPA 1968); every limitation in a count is material and must be proved to establish an actual **reduction** to **practice**. *Meitzner v. Corte*, 537 F.2d 524, 528, 190 USPQ 407, 410. See also *Hull v. Bonis*, 214 USPQ 731, 734 (Bd. Pat. Inter. 1982) (no doctrine of equivalents-remedy is a preliminary motion to amend the count to conform to the proofs).

VII. CLAIMED INVENTION IS NOT ACT-UALLY REDUCED TO PRACTICE UN-LESS THERE IS A KNOWN UTILITY

Utility for the invention must be known at the time of the **reduction** to **practice**. *Wiesner v. Weigert*, 666 F.2d 582, 588, 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); *Azar v. Burns*, 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to **practice** unless the composition and the product produced by the method have a practical utility); *Ciric v. Flanigen*, 511 F.2d 1182, 1185, 185 USPQ 103, 105-6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a **reduction** to **practice**"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); *Engelhardt v. Judd*, 369 F.2d 408, 411, 151 USPQ 732, 735 (CCPA 1966) (When considering an actual **reduction** to **practice** as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); *Rey-Bellet v. Engelhardt,* 993 F.2d 1380, 1384, 181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and **reduction** to **practice**: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

VIII. A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (**Reduction** to **practice** was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record

established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 628 F.2d 853, 858, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual **reduction** to **practice**.).